

## § 111.1

111.325 Under this subpart J, what records must you make and keep?

### **Subpart K—Production and Process Control System: Requirements for Manufacturing Operations**

111.353 What are the requirements under this subpart K for written procedures?

111.355 What are the design requirements for manufacturing operations?

111.360 What are the requirements for sanitation?

111.365 What precautions must you take to prevent contamination?

111.370 What requirements apply to rejected dietary supplements?

111.375 Under this subpart K, what records must you make and keep?

### **Subpart L—Production and Process Control System: Requirements for Packaging and Labeling Operations**

111.403 What are the requirements under this subpart L for written procedures?

111.410 What requirements apply to packaging and labels?

111.415 What requirements apply to filling, assembling, packaging, labeling, and related operations?

111.420 What requirements apply to repackaging and relabeling?

111.425 What requirements apply to a packaged and labeled dietary supplement that is rejected for distribution?

111.430 Under this subpart L, what records must you make and keep?

### **Subpart M—Holding and Distributing**

111.453 What are the requirements under this subpart M for written procedures?

111.455 What requirements apply to holding components, dietary supplements, packaging, and labels?

111.460 What requirements apply to holding in-process material?

111.465 What requirements apply to holding reserve samples of dietary supplements?

111.470 What requirements apply to distributing dietary supplements?

111.475 Under this subpart M, what records must you make and keep?

### **Subpart N—Returned Dietary Supplements**

111.503 What are the requirements under this subpart N for written procedures?

111.510 What requirements apply when a returned dietary supplement is received?

111.515 When must a returned dietary supplement be destroyed, or otherwise suitably disposed of?

111.520 When may a returned dietary supplement be salvaged?

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111.525 What requirements apply to a returned dietary supplement that quality control personnel approve for reprocessing?

111.530 When must an investigation be conducted of your manufacturing processes and other batches?

111.535 Under this subpart N, what records must you make and keep?

### **Subpart O—Product Complaints**

111.553 What are the requirements under this subpart O for written procedures?

111.560 What requirements apply to the review and investigation of a product complaint?

111.570 Under this subpart O, what records must you make and keep?

### **Subpart P—Records and Recordkeeping**

111.605 What requirements apply to the records that you make and keep?

111.610 What records must be made available to FDA?

AUTHORITY: 21 U.S.C. 321, 342, 343, 371, 374, 381, 393; 42 U.S.C. 264.

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## **Subpart A—General Provisions**

### **§ 111.1 Who is subject to this part?**

(a) Except as provided by paragraph (b) of this section, you are subject to this part if you manufacture, package, label, or hold a dietary supplement, including:

(1) A dietary supplement you manufacture but that is packaged or labeled by another person; and

(2) A dietary supplement imported or offered for import in any State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

(b) The requirements pertaining to holding dietary supplements do not apply to you if you are holding those dietary supplements at a retail establishment for the sole purpose of direct retail sale to individual consumers. A retail establishment does not include a warehouse or other storage facility for a retailer or a warehouse or other storage facility that sells directly to individual consumers.